

## **Horizon Scanning Protocol and Operations Manual**

**Prepared for:**

Agency for Healthcare Research and Quality  
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## **Statement of Funding and Purpose**

A statement regarding funding and purpose will be included in reports from the activities of the U.S. Agency for Healthcare Research and Quality (AHRQ) Healthcare Horizon Scanning System. The work is being performed by ECRI Institute under contract to AHRQ, Rockville, MD (Contract No. HHSA29020100006C). The findings and conclusions in this document are those of the authors, who are responsible for its content, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

A novel intervention may not appear in the reports simply because the System has not yet detected it. Inclusion or absence of novel interventions in the Horizon Scanning Reports will change over time as new information is collected. This should not be construed as either endorsements or rejections of specific interventions.

A representative from AHRQ served as a Contracting Officer's Technical Representative and provided input during the implementation of the horizon scanning system. AHRQ did not directly participate in the horizon scanning, assessing the leads or topics, or provide opinions regarding potential impact of interventions.

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## **Financial Disclosure Statement**

None of the investigators has any affiliations or financial involvement that conflicts with the material presented in this report.

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## Preface

The purpose of the AHRQ Healthcare Horizon Scanning System is to conduct horizon scanning of emerging health care technologies and innovations to better inform patient-centered outcomes research investments at AHRQ through the Effective Health Care Program. The Healthcare Horizon Scanning System provides AHRQ a systematic process to identify and monitor target technologies and innovations in health care and to create an inventory of target technologies that have the highest potential for impact on clinical care, the health care system, patient outcomes, and costs. It will also be a tool for the public to identify and find information on new health care technologies and interventions. Any investigator or funder of research will be able to use the AHRQ Healthcare Horizon Scanning System to select potential topics for research.

The health care technologies and innovations of interest for horizon scanning are those that have yet to diffuse into or become part of established health care practice. These health care interventions are still in the early stages of development or adoption except in the case of new applications of already-diffused technologies. Consistent with the definitions of health care interventions provided by the Institute of Medicine and the Federal Coordinating Council for Comparative Effectiveness Research, AHRQ is interested in innovations in drugs and biologics, medical devices, screening and diagnostic tests, procedures, services and programs, and care delivery.

Horizon scanning involves two processes. The first is the identification and monitoring of new and evolving health care interventions that are purported to or may hold potential to diagnose, treat, or otherwise manage a particular condition or to improve care delivery for a variety of conditions. The second is the analysis of the relevant health care context in which these new and evolving interventions exist to understand their potential impact on clinical care, the health care system, patient outcomes, and costs. It is NOT the goal of the AHRQ Healthcare Horizon Scanning System to make predictions on the future utilization and costs of any health care technology. Rather, the reports will help to inform and guide the planning and prioritization of research resources.

We welcome comments on this Protocol and Operations Manual. Send comments by mail to the Task Order Officer named in this report to: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by e-mail to [effectivehealthcare@ahrq.hhs.gov](mailto:effectivehealthcare@ahrq.hhs.gov).

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# Introduction

Horizon scanning is an activity undertaken to identify technological and system innovations that could have important impacts or bring about paradigm shifts. In the health care sector, horizon scanning pertains to identification of new (and new uses of existing) pharmaceuticals, medical devices, diagnostic tests and procedures, therapeutic interventions, rehabilitative interventions, behavioral health interventions, health care delivery innovations, and public health and health promotion activities. Health care horizon scanning has typically been performed to inform a variety of strategic planning activities. Formal or informal health care horizon scanning programs have long been used by public or private entities around the world for various purposes, including commercial planning, health service research prioritization, financial or operational planning, controlled diffusion of technologies, and provision of information to policy makers, purchasers, and providers of health care. For example, hospitals and health care facilities have used horizon scanning information to inform their five-year technology acquisition plans to better understand how their clinical service lines might be affected or disrupted by new innovations. Health insurance companies have used horizon scanning information to prepare for coverage decisions they anticipate needing to make in the future. Some, such as the EuroScan horizon scanning (or “early alert”) systems, may also inform decisions regarding primary or secondary research (e.g., Health Technology Assessment).

In early 2010, the Agency for Healthcare Research and Quality (AHRQ) identified an immediate need to establish a national Healthcare Horizon Scanning System to generate information to inform comparative effectiveness research investments made through its Effective Health Care (EHC) Program. Those investments are made in 14 priority areas for which AHRQ commissions comparative effectiveness reviews and research. For purposes of horizon scanning within those priority areas, AHRQ’s interests are broad and encompass drugs, devices, procedures, treatments, screening and diagnostics, therapeutics, surgery, and care delivery innovations—which are referred to generically as “interventions” in the AHRQ Healthcare Horizon Scanning System.

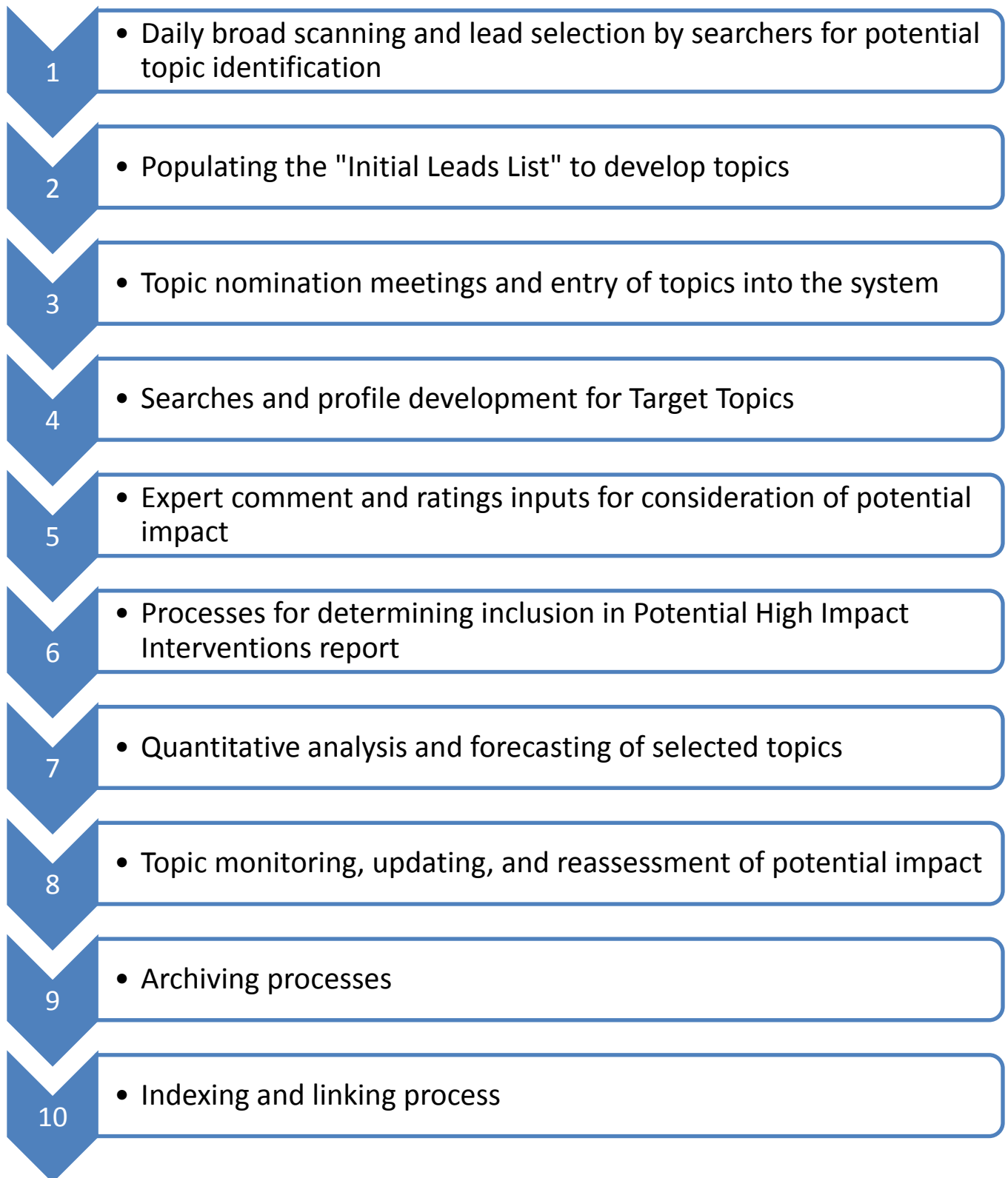
AHRQ has identified the following goals for its health care horizon scanning activities:

1. To create and use transparent and clearly defined processes to identify and monitor novel interventions or new uses of existing interventions in health care that might address an unmet need.
2. To develop and implement a transparent and clearly defined framework for identifying which interventions could have the highest potential impact on clinical care, the health care system, patient outcomes, and costs.
3. To evaluate components of existing horizon scanning systems and their respective protocols to identify best practices and effective methods of horizon scanning.

Prior to this initiative, no publicly available, comprehensive system existed for horizon scanning in the United States. AHRQ, therefore, implemented a horizon scanning framework and infrastructure that builds on prior private sector work to identify, monitor, and assess target technologies in health care but also includes new methods for determining potential impacts. Although some of the horizon scanning

methods and procedures developed for other countries may be applicable in the United States, the ARHQ Healthcare Horizon Scanning System takes into account the unique characteristics of health care in the United States. This document outlines the basic protocol and decision processes that are being followed in broad scanning to identify leads for new interventions, to select topics for in-depth information searches, and to identify interventions that could have the greatest potential impact in each priority area within two years of their availability for diffusion into clinical practice. An overview of these processes is shown in Figure 1.

**Figure 1. Healthcare Horizon Scanning System Process Overview**



# **Unified Process and Decision Algorithm for the AHRQ Healthcare Horizon Scanning System**

Herein we describe the process and decision points for the AHRQ Healthcare Horizon Scanning System. Because certain terminology is limiting in terms of what we are scanning for and identifying, we use the generic term “intervention” to encompass drugs, devices, procedures, surgeries, care delivery innovations, diagnostics, and treatments.

## **1. Daily broad scanning and lead selection by searchers for potential topic identification**

To identify potential topics, ECRI Institute’s Information Center has implemented a tiered scanning and search system. The center is staffed by medical librarians (also called searchers) and feeds leads to a team of horizon scanning analysts. As related leads aggregate, analysts develop topics. (See step 2.) At the outset, for the broadest level of scanning performed for each priority area, the process integrates external inputs with searching and scanning done by the Information Center. The searchers access public and proprietary resources in the health, scientific, and business spheres to scan for new developments in all facets of health care-related topics. (See Appendix A. Table 1) These include, but are not limited to, ECRI Institute’s own research publications and the questions it receives from hospitals, health plans, and other entities that use the organization’s services; blogs; aggregated news sources (e.g., PR Newswire health and science industries); and repositories of peer-reviewed journals (both general medical and specialty journals) and gray literature (e.g., government-issued documents; manufacturer-issued documents; health care and medical science trade publications and newsletters; other health care information published outside the peer-reviewed journal literature). Conference proceedings from meetings of professional societies and other organizations (e.g., trade associations, industry associations) identified through press releases are evaluated and added to the scanning list if they are found to yield high-quality relevant information.

Resources are reviewed initially without employing a search strategy. When possible, distribution of publications is customized (for example, using RSS feeds) to send daily email updates and electronic tables of contents to horizon scanning team members or to allow team members to set alerts that will notify them when a new issue or new content is available. Individual resources, such as those listed in Appendix A. Tables 1 - 5

Table 1 are assigned to the medical librarians who are responsible for creating their own alerts and reviewing content regularly. They create a scanning schedule for resources that do not offer an updating option. Such resources are reviewed daily, weekly, monthly or quarterly depending on their publication schedule.

Items of interest are downloaded in electronic format and posted to a leads management document library. At this point, the medical librarians assign one or more “tags” to the items. The tags include the



names of the 14 priority areas and 1 area designated “cross-cutting” by ECRI Institute for interventions that affect many or all priority areas (see Priority Area list below). Additional tags may be added to a lead to denote subcategories within a broad priority area (e.g., breast cancer, peripheral artery disease, type I diabetes).

Scanning of peer-reviewed medical and scientific journals is also part of the broad search in the priority areas to identify potential leads. The databases searched (see Appendix A, Table 2) and subject-specific search strategies tailored to each of the priority areas are developed and adapted for the syntax of each search platform (as in the example in Appendix A, Table 3). In addition, separate filters are applied that are intended to identify general process and health care delivery innovations and new interventions and new uses of existing interventions (see Appendix A, Table 4).

### ***Daily leads reviewed and selected by searchers performing broad scans***

Searchers use the criteria described on the following pages to guide lead selection from their broad scans. To cast as wide a net as possible, searchers “select” a potential lead if they are unclear as to whether it meets the inclusion criteria. The decision about whether to pursue a lead is made by the horizon scanning analyst team at a later point (see Step 2.). The team undertakes preliminary general background searching as needed to further research and evaluate leads they receive.

All leads selected by searchers for consideration must pertain to one of the 14 AHRQ-defined priority areas or a cross-cutting area.

#### **Priority Areas**

1. Arthritis and nontraumatic joint disease
2. Cancer
3. Cardiovascular disease
4. Dementia (including Alzheimer’s Disease)
5. Depression and other mental health disorders
6. Developmental delays, attention-deficit hyperactivity disorder, and autism
7. Diabetes mellitus
8. Functional limitations and disability
9. Infectious Disease, including HIV/AIDS
10. Obesity
11. Peptic ulcer disease and dyspepsia
12. Pregnancy, including preterm birth
13. Pulmonary disease/asthma
14. Substance abuse
15. Cross cutting

Sets of questions were developed to inform searchers' and analysts' thinking about whether a lead appears to represent an intervention that is novel, innovative, relevant, and addresses a potentially important unmet need. We define "unmet need" in an extremely broad sense: Any need arising from a gap in effective ways to screen, diagnose, treat, monitor, manage, or provide or deliver care for a health condition or disease. Interventions might be lacking entirely (e.g., treatment for Duchenne muscular dystrophy) or existing options might be less than optimal (e.g., warfarin, deemed too risky for an estimated 40% of patients with atrial fibrillation, or isoniazid, which presents significant risks of hepatotoxicity and cannot be used to treat approximately 20% of patients with tuberculosis). Unmet need also arises from conditions for which significant barriers exist to obtaining effective care, such as heart transplantation, or conditions for which availability of certain treatments is limited by location, access, or cultural or ethnic barriers that could cause health disparities.

A frequently cited example of a technology that addressed an unmet need was the Zostavax vaccine for prevention of some strains of herpes zoster, the cause of shingles. Prior to Zostavax, no effective means of preventing shingles existed. Unmet need also arises from a multitude of barriers to care. Thus, a care process innovation that enables better access to care for an underserved population or a population that is disproportionately affected by a condition and known to have poor health outcomes (e.g., hypertension in African Americans; diabetes in Native Americans) would be considered important because it addresses unmet needs.

We also consider whether a lead relates to an older innovation that never diffused but now appears primed for further development or diffusion because of a "tipping point," i.e., circumstances that make it ripe for development and diffusion. The sets of questions are also meant to help the team filter out interventions that are very similar to interventions already available and diffused, which thus would not address an unmet need. We also provide below reasons why these questions are asked and answered when considering whether a lead should be developed into a topic entered into the AHRQ Healthcare Horizon Scanning System. The five boxes below outline the questions considered for Drugs, Biologics, and Devices; Screening and Diagnostic Interventions; Surgical Procedures; Behavioral Health Interventions; and Health Programs and Health Care Delivery Innovations.

### Questions Considered About Drugs, Biologics, and Devices

1. Is this a new molecular entity (drug), biologic, or generic formulation of a drug being developed for potential diffusion into the U.S. health care system? If so, select. New molecular entities may be a signal of a new class of interventions intended to address a potentially important unmet need. Consider the following when answering this question:
  - a. Is it subject to approval under FDA's Investigational New Drug, Biologics Licensing, combination-product application, or Investigational Device Exemption Premarket Approval processes? If so, select.
  - b. Is it a generic drug? If so, do not select, because these are "me-too" of existing drugs. Is it subject to 510(k) clearance processes? If so, select only if it appears to represent some sort of relevant innovation to address a potentially important unmet need.
2. Is this a human clinical trial of either an apparent novel intervention or a novel way to use an existing intervention, and is it capable of diffusing into the U.S. healthcare system within several years? If so, select. (Animal and in vitro studies are excluded.) Clinical trials may be a signal of some new research question, or unmet need, being studied. Clinical trials also examine interventions that are not subject to regulatory pathways, such as surgical procedures. The additional questions below help to determine if this is the case and also inform the stage of development (and expected time to adoption).
  - a. Is it transitioning from one phase to another?
  - b. Is this a proof-of-concept study?
  - c. Is this a first-in-human study?
  - d. Has a trial been initiated or terminated?
  - e. Are results being reported?
3. Does this appear to be a different/off-label use of a currently available drug, biologic, or device? If so, select. Off-label use may signal an attempt by the clinical community to address an unmet need that is not being pursued by developers or innovators.
4. Is this a professional medical society meeting announcement? If so, should we monitor the meeting annually for new developments? New research about interventions in development to address unmet needs is typically presented at professional society meetings. Meeting abstracts and poster presentations presented in these venues may not appear in the peer-reviewed literature and can be a rich source of leads.
5. Is this a product launch? Such announcements can signal diffusion of an intervention intended to address a potentially important unmet need. Select if it appears to address an unmet need.
6. Is this a regulatory announcement? This includes manufacturers' announcements of intentions to file for regulatory approval/clearance as well as notices from regulatory agencies and advisory panels. These announcements may identify novel or relevant interventions that potentially address an unmet need. Select if it appears to address an unmet need.
7. Is this a different delivery mode for an existing drug or device? Changes in formulation (e.g., from injection administered by a clinician to an oral pill) or dosing regimens (e.g., from daily dosing to once-a-month dosing) are sometimes intended to address potentially important

unmet needs, such as a need to improve patient compliance or access to a therapy. If so, select.

- 8.** Is this being called an innovation? If a developer refers to the intervention as an innovation, scanners may select it for further follow-up by an analyst to determine if it is truly innovative and addresses a potentially important unmet need. Is this an award for an innovative product, procedure or process?

### Questions Considered About Screening and Diagnostic Interventions

1. Is this a novel screening or diagnostic intervention being developed for potential diffusion into the U.S. health care system? These questions aid searchers in determining whether the screening or diagnostic intervention is within the areas of interest that AHRQ is not addressing through other agency initiatives. We consider the following when deciding whether to select:
  - a. If this is the first time the screening or diagnostic testing appears to have been done for the condition, select.
  - b. If this is a new type of screening or diagnostic test that purports to address an unmet need, select.
  - c. If this is an accepted form of screening or diagnostic testing delivered in a slightly different setting, do not select.
  - d. If this is a laboratory-developed test (LDT), do not select unless the developer has expressed intent to create and market a commercial test kit in the United States. (AHRQ has other initiatives examining LDTs and thus LDTs are outside the scope of the Healthcare Horizon Scanning System)
2. Is this a genome-wide association study (GWAS)? If so, do not select. GWAS reflects the earliest research that may one day underpin future development of an LDT or a genetic marker test kit, but these are too early for inclusion in the horizon scanning system.
3. Is this a human clinical trial (animal and in vitro studies are excluded.) for a novel screening or diagnostic approach that purports to address an unmet need? () Consider the following:
  - a. Is it transitioning from one phase to another? If so, select.
  - b. Is this a proof-of-concept study? If so, select.
  - c. Is this a first-in-human study? If so, select.
  - d. Has a trial been initiated (select) or terminated (do not select)?
  - e. Are results being reported? If so, select.
4. Is this a professional medical society meeting announcement about a screening or diagnostic intervention purported to address an unmet need? If so, should we monitor the meeting annually for possible leads?
5. Is this being called an innovation? If so, select.
  - a. Is this an award for an innovative product, procedure or process?

### Questions Considered About Surgical Procedures

1. Is this a different or novel surgical approach or procedure that has potential to diffuse into the U.S. health care system within the next several years? Consider the following when deciding whether to select:
  - a. Have signals of interest by U.S. surgeons or institutions been identified through vehicles such as meeting abstracts, editorials, commentaries, case reports, or press releases?
2. Is this a new and different clinical indication for an existing surgical procedure? If so, select.
3. Is this a surgical procedure that requires use of procedure-specific tools or devices in development? Consider the following when answering this question:
  - a. Are the tools subject to approval under FDA's premarket notification (510k) or Premarket Approval (PMA) application processes or combination-product process? If a 510(k), select only if it enables some sort of relevant innovation in surgery to address an unmet need.
4. Is this a human clinical trial (animal and in vitro studies are excluded.) on a novel surgical approach to address an unmet need? Also consider the following when deciding whether to select:
  - a. Is it transitioning from one phase to another? If so, select.
  - b. Is this a proof-of-concept study? If so, select.
  - c. Is this a first-in-human study? If so, select.
  - d. Has a trial been initiated (select) or terminated (do not select)?
  - e. Are results being reported? If so, select.
5. Is this a professional medical society meeting announcement on a novel surgical approach? If so, should we monitor the meeting annually?
6. Is this being called an innovation in surgery? If so, select.
  - a. Is this an award for an innovative product, procedure or process?

### **Questions Considered About Behavioral Health Interventions**

1. Is this a behavioral intervention that is purported to be a markedly different or novel approach than currently exists to address an unmet need? If so, select.
2. Is this a human clinical trial on a novel behavioral health intervention that purports to address an unmet need? If so, select.
  - a. Is it transitioning from one phase to another? If so, select.
  - b. Is this a proof-of-concept study? If so, select.
  - c. Has a trial been initiated (select) or terminated (do not select)?
  - d. Are results being reported? If so, select.
3. Is this a professional medical society meeting announcement that signals a markedly different or novel approach than currently exists and that purports to address a potentially important unmet need? If so, should we monitor the meeting annually?
4. Has there been a shift or tipping point in an existing, but not previously diffused behavioral health intervention? Does it appear poised to become much more widely diffused for some reason? Is it a novel combination of approaches? If so, select.
5. Is this a program launch of a different or novel program than currently exists and purports to address an unmet need? If so, select.
6. Is this intervention being called an innovation? If so, select.
  - a. Is this an award for an innovative product, procedure or process?

**Questions Considered About Health Programs and Health Care Delivery Innovations**

1. Is this a novel or innovative way of delivering care or a different/new combination of services being developed or adapted and implemented into the U.S. health care system?
2. Is this a new health care-related social service that might affect patient outcomes?
3. Has there been a shift or tipping point causing wider diffusion of an existent but underused approach or constellation of approaches?
4. Is this a human clinical trial of a novel health care program or delivery method purporting to address a potentially important unmet need? Consider the following when decided whether to select:
  - a. Is it transitioning from one phase to another?
  - b. Is this a proof-of-concept study?
  - c. Has a study been initiated or terminated?
  - d. Are results being reported?
5. Is this something that represents a systems shift in health care delivery? If so, select.
6. Is this being called an innovation? If so, select.
  - a. Is it an award for innovation in care delivery?



## 2. Populating the “Initial Leads List” to develop topics

After searchers have collected leads from broad scanning using the above criteria, leads are uploaded to the *Initial Leads List*. This is a document library containing all leads identified by searchers as well as leads generated from signals ECRI Institute receives as an information provider to health care facilities, health systems, and payers inquiring about new procedures and off-label and new uses of existing technologies. ECRI Institute also receives unsolicited suggestions from individuals and entities aware of the project and subjects those suggestions to the same criteria as the leads that searchers identify. The analysts classify leads by topic class (see below). In addition, searchers add priority area sub-classifications as shown in Table 5, Appendix A.

### Topic Classes

- Assistive Technology
- Behavioral Therapy
- Biotechnology
- Care delivery innovation
- Complementary/Alternative Therapy
- Device
- Diagnostic
- Diet/Nutrition
- Implant
- Information Technology
- Nanotechnology
- Pharmaceutical
- Procedure
- Program
- Service
- Surgery
- Other

### *Initial lead sorting and topic identification*

After categorization, leads are assigned to horizon scanning analysts according to the priority areas they are covering. Upon receiving broad scanning results from ECRI’s Information Center, horizon scanning analysts review the results and use the following algorithm (see box below ) to initially assess preliminary leads and create a list of possible topics. The list includes the topic name, the intended patient population, a few sentences describing the intervention, and the unmet need it purports to address.

### Algorithm for Assessing and Sorting Leads to Identify Possible Topics

1. Analysts sort leads by AHRQ Priority Area, Subcategory, and Topic Class.
2. Within each general sort area, the analysts group leads into “topics.” Each *topic* corresponds to a discrete intervention (technology, service, care innovation, new use of existing intervention, new procedure/surgery etc.).
3. Analysts tag each lead with one or more identifiers (e.g., product name, manufacturer name, or program name) related to the technology, service, care innovation, new use of existing service, etc., to enable grouping and sorting of related leads.
4. Each analyst provides a brief descriptor for each lead in a “Notes” field of the *Initial Leads List*. For example, the analyst might include his/her rationale for topic proposal, notes on expected or potential impacts to the health care system, reasons for inclusion/exclusion, technology mechanism of action, competing technologies, etc.
5. The status of the work on each lead is documented by analysts by choosing from a drop down list containing the following items:
  - b. New – The lead was recently uploaded and has not yet been reviewed by an analyst.
  - c. Reviewed – The lead has been reviewed by an analyst, but no formal action has been taken at this point.
  - d. Linked – The lead has been reviewed by an analyst and linked to one or more topics.
  - e. Discarded – The analyst has determined that the lead is irrelevant to the horizon scanning system for any of several reasons (such as, out-of-date, pertains to animals, is a duplicate, does not meet criteria upon their further evaluation). The analyst provides a brief rationale for discarding the lead.
  - f. Archived – The lead had previously been saved or assigned but is no longer relevant for any of several reasons. The analyst provides a brief rationale for archiving the lead (e.g., the lead is out-of-date, superseded by another lead).
6. The analyst may then use various tags to further classify the lead (e.g., lead source, manufacturer name(s), product/intervention name(s), clinical condition, mechanism of action).

### ***Initial topic posting***

As analysts identify potential topics during their initial lead sorting processes, they add the topic to the *Identified Topics List*. The analysts describe topics according to the outline below (see box). Part of the context for thinking about interventions is the “PICO” framework in which analysts describe the potential Patient **P**opulation, **I**ntervention, potential **C**omparators to that intervention, and potential **O**utcomes of interest for the patient population. The horizon scanning analysts then link related leads from the *Initial Leads List* to the appropriate topic in the *Identified Topics List* to enable them to review all leads associated with each identified topic.

#### **Topic Description Outline for Potential Topics**

1. Topic name/title
2. AHRQ Priority Area
3. Topic class
4. Potential/Proposed **P**atient Population (including important disease stage or condition characteristics)
5. **I**ntervention (including, sponsor, developer, or manufacturer)
6. Phase of development and confirmation that it is being developed for potential diffusion into the U.S. health care system (interventions subject to FDA regulation that are earlier than phase III are considered for track-only; interventions with some preliminary phase III or later phase efficacy data are considered for tracking and in-depth information compilation as a Target Topic that will be sent to experts for comment and potential impact rating)
7. Potential **C**omparators (to existing options for the same disease/conditions/patient population, if known at this point in the process)
8. Potential **O**utcomes (i.e., potential health outcomes, potential health system impacts)

### ***Topic selection criteria checklist***

Horizon scanning analysts consider the following criteria. These questions are considered in sequence as they determine whether they can build a case for possible inclusion of the topic in the horizon scanning system. If they can build a case after going through this exercise for each potential topic, the topic will be brought to a topic nomination meeting for discussion and decision making about whether to enter it into the system.

#### **Criteria for Entering Topic Into the Horizon Scanning System**

1. Does the intervention purport to address an unmet need? If yes, describe the unmet need and the potential importance of this unmet need.
2. Is the intervention going to be or already in development for the U.S. health care system? Or, can the intervention be adopted or diffused into the U.S. without going through a regulatory process (e.g., off-label uses, new surgery approaches, care delivery innovations, behavioral health nondrug interventions)? If yes, consider question 3.
3. Is the intervention novel, relevant, or innovative for addressing the need? If yes, consider question 4.
4. Would adoption or implementation of this intervention potentially shift/change/disrupt any of the following? If yes, describe the intervention's potential impacts. In thinking about this, consider the following:
  - a. Potential to change current treatment models
  - b. Disparities in health care among different patient populations
  - c. Paradigm shifts (e.g., in patient management, understanding disease or condition)
  - d. Care setting change
  - e. Health care delivery process change
  - f. Infrastructure needs of the health care system or health facilities
  - g. Patient health outcomes and individual burden of disease
  - h. Population health outcomes and societal burden of disease
  - i. Clinician learning curve to use the intervention
  - j. Patient or non-clinician caregiver to use the intervention
  - k. Costs of care for the disease or condition

### 3. Topic nomination meetings and entry of topics into the system

Horizon scanning analysts nominate topics for entry into the system at Topic Nomination Meetings. To be entered into the system for tracking, topics are assigned: “track only” or “advance to target.” The “track-only” designation means that the intervention is in early to middle phases of clinical development with little or no preliminary safety and efficacy data available. In this case, the horizon scanning search team does not formulate detailed search strategies to perform in-depth searches for information about the topic. Rather, searchers continue to identify related leads and material through their daily scanning, and they link the leads to the topic to enable analysts to follow the status of development. The “advance to target” designation means that searchers devise detailed search strategies and undertake in-depth searches of public and proprietary databases to identify topic-specific information for the analysts. Analysts review and use this information to develop in-depth profiles of Target topics, complete with referenced sources.

Topic nomination meetings typically occur several times a month. Medical librarian searchers, ECRI horizon scanning analysts, the content team leader, the project manager, and other invited staff and experts participate. Analysts present “proposed topics” from their assigned priority areas to the team and invited experts. The topics are granular; that is, they are at a product-specific, procedure-specific, program-specific level. For example, if several candidates in a new class of drugs or devices are in development at the same time, each one is tracked individually during its journey through the system until consideration for the quarterly Potential High Impact Interventions report (see Step 6). In that report, topics are rolled up to the “class” level. For example, each protease inhibitor for treatment of hepatitis C virus would be tracked individually, but the drugs would be discussed as a class if the expert comment process (see Step 5) deemed any of the protease inhibitors to have potential for high impact. Keeping the topics granular when they are being tracked in the system is necessary because evidence development, ongoing trials, regulatory status, and manufacturers differ by individual product, procedure, or program. For example, one company may cease development while another company proceeds to market.

#### **Issues Discussed When Analysts Present Proposed Topics at Topic Nomination Meetings**

1. Rationale for proposing the topic: why the topic seems important overall
2. Brief description of the unmet need the topic addresses
3. Description of how the intervention proposes to meet the need and whether it seems to be novel or innovative
4. Stage of development of the intervention
5. Potential outcomes/areas of impact
6. Potential existing comparators and potential comparators in development

While considering the presentations, team members and any guest attendees with subject matter expertise are instructed to consider the same questions (i.e., topic selection criteria checklist questions above) that the analysts considered when deciding whether to nominate a topic at the meeting. Team discussion takes place for each topic and includes an opportunity to ask questions. Medical librarians participating in the meetings conduct ad hoc searches to address questions. If a question cannot be resolved satisfactorily and quickly during the meeting, the topic is marked for follow-up search after the meeting by a librarian and/or the analyst proposing the topic. The results of that follow up are communicated to the team electronically, a final decision (majority vote by the team) is made on whether to enter the topic into the system, and if the topic is to be entered, a determination of status (track or advance to target) is assigned.

All topic recommendations and their disposition are recorded and voted on. Topics must receive a majority vote to be entered into the system. If vote is a tie, the project manager breaks the tie with an extra vote. If the project manager is absent, the content team leader has an additional vote. During the first 9 months of piloting the system, tie votes occurred less than 1% of the time; close votes occurred less than 5% of the time.

Clinical interventions (i.e., drugs, devices, procedures) that are voted for advancing to target must be far enough along in development (typically phase III) to have some preliminary efficacy and safety data available for inclusion in the profile. Topics that are programs or care delivery innovations may be advanced to target with less data available if enough information is available to describe the care delivery innovation well, and if demonstration projects or pilot studies are underway. Profiles on Target Topics are subsequently submitted to sets of various types of experts from the health care sector. (See Step 5. Expert comment and ratings inputs for consideration of potential impact.) They are asked to read the profile and offer perspectives and opinions about potential impact. Initial pilots of expert commenting processes indicated that experts were uncomfortable and reluctant to comment on impact potential for Target interventions in very early stages of clinical research.

## **4. Searches and profile development for Target Topics**

After each topic nomination meeting, the content team leader adds each new “advance to target” topic for development of a full profile into the *Horizon Scanning Production Queue*. Each Target Topic is assigned to the analyst covering that priority area and to a medical librarian who creates the detailed search strategy and conducts searches. Each individual analyst covers the same AHRQ priority area(s) to maintain continuity and to grow his or her expertise and understanding of the landscape of new developments in that priority area.

### ***Topic-specific searching and reference management***

In developing the strategies and conducting searches, medical librarians decide which resources are appropriate for conducting targeted topic-specific searches. Parallel search strategies are created for every resource searched. The search strategy and results of the searches are recorded on a standardized data entry form that is maintained in the system. Searchers also set up alerts for each Target Topic to begin the ongoing monitoring process for each topic. Alerts go to the searcher for uploading into the system and assignment to the analyst covering that topic.

Members of the database management team standardize search results from public and proprietary bibliographic databases for entry into the citation (reference) management system and also manually create records in the citation management system for information retrieved from non-database sources (such as manufacturer websites). They then deliver these processed results electronically to the analysts’ workflow system.

The database staff also process and manage the analysts’ document requests. They work closely with the library staff to obtain full-text documents electronically, distribute documents electronically to the requesting analyst, record analysts’ requests, document delivery in the citation management system, and generate reference lists based on documents selected by the analysts for inclusion in the profiles they write on Target Topics.

The database staff also enter every set of expert comments (Step 5) received on Target Topics into the document management system, and assigns a reference number to it so that analysts can reference expert perspectives (by expert category) as needed when they synthesize results of the comment process that leads to designations of topics as potential high impact (Step 6).

### ***Development of Target Topic profiles***

After receiving topic-specific search results, the horizon scanning analyst reviews and organizes all materials, selects materials of most relevance for completing a profile, requests additional follow-up searches as needed, and begins drafting a profile. Two templates are used: one for clinical interventions (drugs, devices, procedures, surgery, screening, diagnostic interventions); one for programs and care delivery innovations. The fields of information compiled in each template are presented in the boxes below.

The analyst populates, as fully as possible, the appropriate template. While compiling the information for each profile, the analyst references each source of information so that reference lists can be generated for the profile.

#### **Clinical Interventions Template**

1. Topic Title (intervention name and intended use[s])
2. Potential Importance of This Topic
3. Clinical Pathway for Condition at the Point the Target Intervention Would Potentially Be Used
4. Disease/Condition Description
5. Technology/Service/Care Innovation Name and Description
6. Related Names for New Technology/Service/Care Innovation
7. Potential Care Setting(s)
8. Phase of Development and Comment
9. Ongoing Trials and Evidence Development (Two tables are provided: 1 for ongoing trials and 1 for the study investigators' or developer's reports of preliminary results from the latest phase trials. Results are presented in quotation marks exactly as issued by study authors from meeting abstracts, published articles, or company press releases. They do not reflect any interpretation or analysis on the part of the Horizon Scanning team.)
10. Manufacturers and Regulatory Status (if applicable)
11. Potential Device/Drug Cost Per Patient (if applicable)
12. Clinical Provider(s) and Training/Credentialing Issues
13. Potential Staffing and Infrastructure Implications
14. Potential/Intended Indications/Contraindications
15. Potential Competing and Complementary Technologies/Services for the Disease/Condition
16. Potential Patient and Clinical Staff Safety Issues
17. Coverage, Coding, and Payment Status (if available)
18. Indexing/Linkages
19. Selected Sources



### **Programs/Care Delivery Innovations Template**

1. Topic Title
2. Potential Importance of this Topic
3. Current Approach to Care
4. Background
5. Program or Intervention Developer
6. Target Population
7. Program or Intervention Description
8. Related Names
9. Potential Program or Intervention Setting(s)
10. Level of Diffusion and Comment
11. Evidence Development and Ongoing Clinical Trials (if available)
12. Recently Completed Trials (if available)
13. Intended Provider(s) and Potential Training Requirements
14. Patient Safety Issues (if applicable)
15. Required Resources
16. Cost, Funding, and Reimbursement Considerations
17. Potential Competing and Complementary Programs or Interventions
18. Indexing/Linkages
19. Selected Sources

## **5. Expert comment and ratings inputs for consideration of potential impact**

We have recruited experts in the health care system to provide comments and ratings on potential impact of topics on the basis of their subject matter expertise. Our database currently contains contact information and areas of expertise for about 350 experts. Experts are clinical or research subject matter experts; or they may be experts on health systems, health disparities, health care practices, health technology and services assessment, comparative effectiveness research, health business issues, or health administration. (See additional details of expert selection below.) We seek as participants front-line clinical specialists, generalists, and health systems and health administration professionals working in all sizes of health systems and settings (urban, rural, and suburban). We seek as participants researchers whose backgrounds and activities indicate broad knowledge of their fields. We obtain comments from U.S.-based experts because they are presumed to be most familiar with the U.S. health care system, and they are better able to respond to the parameters we ask about on the comment/rating form. Recruitment of additional experts is ongoing to expand the pool of participants. While we currently ask experts for their opinions about patient acceptance or adoption of an intervention, we are also considering meaningful ways in which we might include patient perspectives in the future.

As horizon scanning analysts compile material on a Target Topic, they identify and nominate a blend of experts from our database or they suggest additional experts they have identified from the literature or who have been referred to us by other experts in our database. We then solicit the experts we believe could potentially provide useful insight and commentary on the specific topic. The group of experts commenting on any particular topic usually differs, even among related topics. For example, a biologic in development for many types of cancers may have some expert commentators in common for the health systems and health business perspectives, while other experts will be unique to the clinical condition (e.g., lung cancer versus liver cancer).

Seven experts are sought to provide perspectives about each topic using a topic-specific structured comment form. (See Appendix B.) At times, because many potential experts are sought at once to achieve the desired number of seven experts with a range of perspectives, as many as eight experts' comment sets may actually be received. (The system accepts a maximum of eight experts for an individual topic.) Three to four of these experts are chosen from among ECRI Institute's own experts (excluding the horizon scanning analysts who compiled the information on a topic), who all adhere to rigorous conflict of interest rules that prohibit ownership of any drug or biotechnology or device company stock investments, or acceptance of any gifts or grants from the medical product industry as a condition of employment.

Three to four external experts are selected for each topic from either the database or from a new solicitation for participation as an expert commentator, as needed. An outline of the type of information sent to experts for comment is shown in the box below.

#### **Information Sent to Experts for Comment**

1. The information compiled on the Target Topic
2. Instructions by e-mail
3. A topic-specific structured form that includes a “Potential Impact” scoring form with parameters and definitions and a Conflict-of-interest (COI) declaration (See Appendix B.)

We request CVs from all external experts in addition to the information we collect on the COI form. Management of potential conflict of interest is discussed further in a subsequent section of this protocol. Each group of the topic-specific experts is instructed to do all of the following:

1. Read the information provided.
2. Provide comments and ratings with supporting rationales for each of seven parameters listed below
3. Score his/her impression of each parameter using a 1 to 4-point scale (with definitions provided).
4. Support each parameter score with a brief rationale.

The expert submits comments and ratings online by clicking on a “submit” button at the end of the form. The form and its content are automatically logged into a database that is a repository for all the experts’ comments and ratings. Although a maximum of seven experts is sought for each Target Topic, a topic becomes eligible for consideration in the Potential High Impact Interventions Report (Step 6) after a minimum of five experts have commented on a topic, including at least two external (to ECRI) experts. The experts’ comments remain in the database for subsequent analysis and synthesis for the next quarterly iteration of the Potential High Impact Report. In the report, experts are identified by their respective role (e.g., clinical, research, health systems).

Approximately 60 new topics are sent out for expert comment and ratings each quarter. Those topics are then taken into consideration with topics that have already received expert comment. Target Topics in the system that completed the expert comment phase may be reissued (Step 8) to obtain updated expert comments when we become aware of important new information that could change/inform an expert’s perspective, such as reports of new data from ongoing or completed trials that could move the development of the intervention forward. In this situation, we solicit the same set of experts who previously commented on the topic. If a Target Topic ceases development or if its development is placed on hold, it is not resent to experts for additional comments unless and until its development restarts. If a Target Topic that was included in the preceding Potential High Impact report halts development or if development is placed on hold pending decision making by the developer, we remove it from the report. (Please see Steps 8 and 9 on “Topic monitoring, updating, and reassessment of potential impact” and “Archiving processes.”)

### ***Expert comment process management***

Provider Resources, Inc. (PRI), a subcontractor to ECRI Institute manages the logistics of the expert comment processes, including solicitation of experts selected by the horizon scanning team for each topic, follow-up to ensure that experts who agreed to provide comments submit them when needed, and documentation of experts' information for the system.

The experts provide diverse general and specialty clinical, research, and health systems perspectives. Experts are selected on a topic-by-topic basis with a goal of achieving a balance of general and specialty expertise and health systems and health business perspectives. The AHRQ Healthcare Horizon Scanning System expects to process expert comments for more than 350 Target Topics in its first year and comments for up to 240 Target Topics in each subsequent year.

Experts reading the compiled information and rating the potential impacts of a Target Topic provide their independent expert opinions based on their respective knowledge about technology/services and the health care system. No individual's comments are intended to represent an entire group or field. Individual experts' scores for the seven parameters are intended to capture qualitative perspectives in a given field/area at a given point in time. It is possible, even likely, that a particularly knowledgeable expert could have an intellectual or financial conflict of interest in a topic on which he or she provides comments.

### ***Balancing any potential conflicts of interest from experts***

Experts are asked to declare any and all potential conflicts of interest (intellectual and financial) on the structured comment form they are required to use when commenting. Those who declare potential intellectual or financial conflicts of interest for a topic are not necessarily disqualified from participating. Their views are balanced by inputs from other neutral parties, including ECRI experts. Those with vested interests in new technologies, services, and innovations typically provide critical insights and information about the areas in which they have a vested interest. Their perspectives include their vision and plans for how they intend to carry out diffusion of a technology, service, or innovation. Out of a total number of seven or eight experts per topic, we limit to two the participation of experts with potential conflicts of interest. The expert with a potential conflict of interest and relatively lesser expertise, based on our assessment of their degree of technical/scientific knowledge by looking at their curriculum vita and publications in the field, is replaced to keep the number with conflicts of interest to one or two. Equally important is identifying whether any experts represent special interests against the technology or service. If they are involved in a competing service or product, their views must also be balanced by experts without special interests and by competing interests.

## **6. Processes for determining inclusion in Potential High Impact Interventions report**

The purpose of the expert comment and rating process is to aid determination of interventions that have potential for high impact on health care utilization, patient outcomes, costs, disparities and access, infrastructure, and systems of care delivery. The currently used parameters were devised based on extensive unstructured, open feedback and suggestions received from the AHRQ Healthcare Horizon Scanning System Expert Panel convened in June 2011 and from more than 40 experts who served in the initial pilot comment and ratings process of 285 topics during the first six months of implementation of the system (December 2010 – May 2011).

### ***Parameter considerations***

From the pilot, we learned that having a relatively small number of broad parameters provides an opportunity for all types of experts to respond to some aspect of the parameter without imposing a burden on experts in terms of their time commitment. The current parameters are intended to provide an opportunity for experts to explore their thinking about a topic on the aspects of most interest to AHRQ. For any given topic, some experts may be more or less expert on some aspects of the topic. For example, researchers may have less expertise about potential health systems or infrastructure impacts, but more expertise on the potential patient outcomes. The purpose of the 4- point scoring system is to serve primarily as a tool to help experts consider various aspects of the topic and to draw out their perspectives. The parameters are worded so that the scale goes in the same direction for each parameter.

### ***How Expert Comments and Scores Are Used***

The overall potential impact of a Target intervention is determined based on consideration of the comments and scores given by experts for each topic. The sets of topic comments are sorted and considered for selection for the quarterly Potential High Impact Report for each AHRQ priority area. Each quarter, the results of the comment and ratings processes for *all* active Target Topics in the system that have completed the process are considered. The list of topics eligible for consideration may grow or shrink depending on the Target intervention's development or diffusion status and experts' comments and parameter scores.

ECRI calculates the mean and median scores for all active Target Topics that completed the required number of expert comments. The starting point for examining topics for potential inclusion in the Potential High Impact Report is the analysts' assessment of comments for those topics with scores at or above the mean and median score for that priority area. The comments take priority over scores because individual experts with similar rationales may actually score a topic differently. Thus, scores are used only as a preliminary signal of potential impact. Furthermore, expert comments for all Target Topics are read—including those scoring below the mean or median in a priority area—to ensure that no topic with important potential is missed because of a scoring anomaly.

AHRQ has requested that up to 20 topics with Potential High Impact be identified in each of the 14 priority areas. It is important to note that the Target Topics with highest potential impact for each priority area are relative to the assessment of the other topics in that priority area at a particular point in time. Some of the priority areas (e.g., substance abuse, pulmonary) may not have 20 Target interventions in development (i.e., that met the system's inclusion criteria) or that merit designation as "potential high impact." Thus, the designation of potential high impact is relative to the range of Target interventions in development that have met criteria for inclusion in the AHRQ Healthcare Horizon Scanning System. "Potential High Impact" reports are generated quarterly and are drawn from the set of active topics in the Target Topic database that completed the expert comment and ratings process at that time. Thus, some number of included topics can be expected to change in any given quarterly "Potential High Impact Interventions" report.

## **7. Quantitative analysis and forecasting of selected topics**

After the database of active Target Topics is populated with a sufficient number of topics (i.e., a minimum of 20 topics per priority condition), we may undertake quantitative modeling of certain topics considered by experts to have potential for high impact. Such quantitative analysis may help to project potential impacts on utilization and cost. Quantitative forecasting may be appropriate when sufficient quality data are available to create a model that yields meaningful output on parameters of interest to AHRQ and the entities AHRQ's research is intended to support. Quantitative modeling outputs are most meaningful when a technology or service is in later phases of development or on the cusp of diffusion because more data will likely have accumulated to use in the model. Modeling may not be appropriate for many early phase interventions. A separate protocol for incorporating quantitative models will be posted at a later date if AHRQ moves forward with this activity.

## 8. Topic monitoring, updating, and reassessment of potential impact

All topics “Tracked” within the *Identified Topics List* and the *Target Topic Database* are monitored daily for new information by the horizon scanning team. To do this, searchers craft strategies using keywords and controlled vocabulary terms for each searchable resource. Wherever possible, searchers create automated alerts to capture new information on an ongoing basis. New information pertaining to tracked topics is entered into the *Initial Leads List* and assigned to the appropriate analyst for review. The searcher then links the item to the topic in the *Identified Topics List* and the analyst reviews the existing topic entry in that list.

If the topic is currently included in the Target Topic database, the analyst reviews the current entry in the database and updates it to reflect the new information.

Analysts update topics on a rolling basis as new information becomes available.

### **Triggers For Updates of Topics Including, But Not Limited To:**

1. New data from conferences or published articles reporting different results or confirming efficacy and safety endpoints
2. Start of new trials on the topic
3. Major changes in adoption and/or implementation issues
4. Company mergers that affect product development (product development may be delayed or halted altogether)
5. Company financing or selling of R&D rights for a product
6. Recommendations for regulatory approval/disapproval from FDA advisory committee meetings,
7. Rapid increase in the volume and sources of published literature on a procedure or care innovation (e.g., uptick in reports on a surgical approach such as single incision laparoscopic surgery; uptick in gray literature on “evidence-based hospital design”)

If the topic is one of those being tracked in the Initial Topics List, the analyst determines whether the new information could change his or her answers about addressing an unmet need or potential shifts, changes, or disruption to some aspect of patient care or the health system.

If so, the analyst takes appropriate action as described previously and re-proposes the topic during the topic nomination meeting. This triggers a vote on whether the Tracked Topic should become a Target Topic and should be progressed through the rest of the process from Step 4.

We conduct active searches for any topic “tracked” within the *Target Topic Database* if no new information from scanning activities has been added during the previous 9 months.



Updates in and of themselves do not necessarily mean that new expert comments are needed to determine impact. If the new information confirms perspectives and comments already received, then the topic is not sent for re-review. However, if the horizon scanning team concludes that the new information could change perspectives, then the Target Topic is reissued for comment by the same experts initially providing comment.

If the analyst answers “YES” to at least one of the signals in the box below, the topic is placed in queue for reissuing a request for expert comment and ratings for potential high impact. Comments are resolicited from the same experts who previously provided comments on the topic. If all the same experts are not available, substitutions are selected to obtain the type of perspective (e.g., clinical, health system, research) the unavailable expert had provided.

**Possible Signals Warranting Resolicitation of Expert Comments**

1. Are there new data that have shed new light on an intervention, such as
  - a. Additional, stronger, confirmatory data that could change perspectives on potential impact
  - b. Safety data that could change perspectives
  - c. New data that are inconsistent with prior data provided to experts?
2. Has a patient safety alert been issued that could signal a safety/efficacy change in perspectives?
3. Has FDA issued a decision that could affect experts’ perspectives, such as a Complete Response Letter from FDA to a developer/manufacturer, who then decides to continue development and initiate new trials that could change expert perspectives, or an advisory panel’s negative recommendation?
4. Are there post-market events (within 2 years of FDA approval) that could change the premarket projections of impact, such as a much slower uptake than anticipated; apparent lack of acceptance by clinicians or patients; no reimbursement; access issues; position statements by professional societies; market withdrawal of competing interventions?

## 9. Archiving processes

During weekly team meetings and during the process for producing the bimonthly Status Update report of all interventions tracked in the system, the Horizon Scanning team also determines whether topics need to be archived.

### Reasons for Retiring and Archiving Topics

1. Product/intervention failure to meet endpoints in trials and product development ceases.
2. Exhaustion of companies' financial resources to continue development
3. Intervention diffusion now 2 years post regulatory approval or, if not subject to FDA regulation, well beyond early adopters for the indication being tracked.
4. Topic is no longer novel or innovative because other topics in its class have reached diffusion in the health care system, rendering the topic a "me-too" that no longer addresses an unmet need.
5. Topic has completed expert comment and ratings, and experts have concluded that the topic has no potential for high impact in any of the parameters of interest to AHRQ or the entities its research supports.
6. Topic has completed expert comment and ratings, and the aggregated comments indicate the intervention is not novel or innovative, or does not address an unmet need, or is not being developed for diffusion into the U.S. health care system, or has little to no potential for high impact in key areas of patient outcomes, utilization, costs, health care system infrastructure, etc.

Maintaining an archive accessible to end-users is important for context over the long term. An archive provides a reference source from which to draw connections about other developing, possibly related technologies; it can inform the likelihood of success and impact for a closely related technology. A technology on hold for a long period can also re-emerge, and archiving provides historical context.

The horizon scanning protocol enables understanding of trends over time, such as how new indications for existing technologies/services/approaches to care emerge, how groups of technology move in tandem, and how they impact the health system, clinical care, patient outcomes, and costs. Examples that illustrate this point include development of high-end imaging technology (PET and CT) and development of minimally invasive surgery approaches with subsequent development of new technologies further enabling those approaches.

## 10. Indexing and linking process

Appropriate content indexing is critical to enable end-users of the Healthcare Horizon Scanning System to accurately and efficiently retrieve information. Controlled vocabularies, including Medical Subject Headings (MeSH), those currently used at AHRQ's Effective Health Care website, and ECRI's Universal Medical Device Nomenclature System (UMDNS), which has been part of the National Library of Medicine's Unified Medical Language System (UMLS) since 1992, are used to index and link content in all the reports produced for the AHRQ Healthcare Horizon Scanning System. These include the Healthcare Horizon Scanning System Status report, the Potential High Impact report, Target technology reports, and Existing Technology reports. Indexing strategies (see below) and the fields in the report templates would support facile transition to a relational database in the future should AHRQ want to pursue that for the Healthcare Horizon Scanning System.

### **Indexing/Linkages**

- Technology class
- Clinical category
- Clinical specialty
- UMDNS if applicable
- MeSH
- ICD9
- FDA SPN
- SNOMED CT

## Appendix A. Tables 1 - 5

**Table 1. Medical web sites, newsletters, trade publications, and peer reviewed publications reviewed by ECRI Medical Librarians**

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
ACM TechNews 2, 3, 4, 8	Digital newsletter published 3x weekly; Summarizes current news on established and emerging areas of computer science, trends in information technology, and related science, society, and technology news. Links directly to source article		X				X	X
AdvaMed 2, 3, 4, 5, 8	Advocacy group for medical device industry. News, information on issues & advocacy efforts, case studies on various technologies AdvaMed SmartBrief, is a daily e-mail summarizing top medical technology news		X		X		X	X
Advances in Pharmacy ASHP Daily Briefing 2, 3	Daily email briefing summarizing key medical and health care news from the previous 24 hours. Targeted to health-system pharmacists			X	X			
AHA Emerging Science Series 1	Online forum for late-breaking clinical trials, key updates of previously presented trials, late-breaking science, new analyses or substudies, major bench-to-bedside breakthroughs and more	X	X	X	X	X		
AlphaGalileo 3	Distributor of news releases and other information from science, health, technology, the arts, humanities, social sciences and business	X	X	X	X	X		X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
American Laboratory 2, 3, 4,5, 8	Digital monthly publication focused on the practice of analytical chemistry. Industry news and information about scientific instrumentation in analytical/ bioanalytical chemistry, basic research, applied spectroscopy, chromatography, petrochemicals and material science	X	X		X		X	X
American Medical News 2,4,5	News publication for physicians published by the American Medical Association covering information on political/regulatory issues, the medical profession, public health, the medical marketplace and practice management.					X	X	X
Archives of Internal Medicine 1, 4, 5, 7, 9	Bi-monthly peer-reviewed journal from the American Medical Association. Publishes original medical research targeted to internists practicing as generalists or medical subspecialists	X	X	X	X	X	X	X
Becker's Hospital Review 2, 4, 5	Cutting edge business and legal information for hospital and health system leaders, owners and operators of ambulatory surgery centers and leaders of orthopedic and spine practices.					X	X	
BioPhotonics 2, 3,5, 7, 8	Monthly digital magazine reporting on developments and techniques in photonics relevant to medicine / biotechnology. Feature articles and industry, product and business news	X	X					X
BizJournals 2,4, 5, 7	Digital weekly business newspapers from 41 major US cities	X	X	X				X
BMJ 1, 2, 4, 5,6, 7, 9	Digital weekly journal. Publishes original medical research to improve patient outcomes and influence the debate on health care. Continuously updated website	X	X	X	X	X	X	X
Body Image 1, 5	Journal that publishes original scientific research on body image and physical appearance			X		X	X	X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Business Week 2, 3, 5, 6	Weekly magazine that reports on international business, financial and investment news	X	X	X		X	X	X
CADTH Health Technology Update & CADTH Issues in Emerging Technology 1, 2,4,8	<i>HTU</i> : Digital newsletter from the Canadian Agency for Drugs and Technologies in Health; reports on new/emerging health care technologies in Canada; provides updates/ links to recent Canadian health technology assessments, recommendations, and clinical practice guidelines; <i>Issues in Emerging Technology</i> : bulletins describing emerging drug and non-drug technologies not yet used or widely used in Canada; Health Canada's approval is usually anticipated within six to 18 months	X	X	X	X	X	X	
California HealthCare Foundation (CHCF) 1, 4	A nonprofit grant making philanthropy focused on clinical outcomes and quality of life, reducing barriers to efficient, affordable health care, promoting transparency and accountability and implementing health reform in California.					X	X	
CancerNetwork 1, 2, 6, 8, 9	Website that aggregates medical information on cancer treatment including original medical research and news updates	X	X	X	X	X	X	X
CanGeneTest 1, 2	Biweekly e-newsletter reporting on genetic laboratory services and clinical use of molecular diagnostic tests ; links to original research and news							X
Cardiology Today 1, 2, 4, 8, 9	Information source for cardiovascular medicine professionals; reports on emerging technologies, techniques and medical therapies, and clinical, therapeutic, industry and socioeconomic issues	X	X	X		X		X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Cardiovascular Update 1, 2	E-newsletter from the Mayo Clinic reports on cutting-edge diagnostic and therapeutic techniques offered in their subspecialty clinics	X	X	X		X		X
Circulation 1, 2, 4, 5, 7, 9	Peer-reviewed journal from the American Heart Association that publishes original medical research related to cardiovascular issues	X	X	X	X	X	X	X
Clinica 2, 4, 6, 8	E-newsletter updated daily; reports on the international devices and diagnostics industries; includes abstracts of relevant scientific research	X	X	X		X	X	X
Clinical Care Options 9, 11	Online medical education programs, technologies and guidelines for HIV, hepatitis/ gastroenterology, hematology/ oncology	X	X	X	X	X	X	X
CMS Coverage e-mail updates 10	E-mail notification of new NCDs or MedCac meeting announcements	X	X	X	X	X		
CMS Updates to Coverage Pages 8, 10	Updates to coverage delivered via email	X	X	X	X	X	X	
Commonwealth Fund 1, 4	A private foundation that promotes a high performing health care system, particularly for society's most vulnerable by supporting independent research on health care issues and making grants to improve health care practice and policy.						X	
Conferences 1	Relevant medical and health care conference abstracts, as they arise.	X	X	X	X	X	X	X
Diabetes Technology & Therapeutics 1, 4, 5, 7	Monthly journal that publishes scientific research on new devices, drugs, drug delivery systems, and software for managing patients with diabetes	X	X	X	X	X		X
Diagnostic Imaging 2, 6, 8 11	Digital newsletter and website providing news and information about radiology		X			X	X	X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
ECRI Institute Health Technology Forecast database 1, 2, 8, 11	Profiles with impact radars, conference reports, news briefs about drugs, devices, procedures in late phase development	X	X	X	X	X	X	X
ECRI Institute Health Technology Trends 2, 4, 5, 8	Monthly newsletter about new developments in health care technologies, processes of care, and factors affecting diffusion and adoption of new interventions	X	X	X	X	X	X	X
ECRI Institute Hotline Responses 1, 4, 8	Researched responses to questions from ECRI Institute member hospitals, health plans, and other subscribing organizations about efficacy and effectiveness of health care technologies, services, and factors affecting diffusion and implementation	X	X	X	X	X	X	X
EurekAlert! 3	American Association for the Advancement of Science (AAAS) portal for press releases from universities, medical centers, journals, government agencies, corporations and other organizations engaged in research	X	X	X	X	X	X	X
European Radiology 1	Peer reviewed journal that publishes original scientific research and reviews in radiology		X			X	X	X
FDA Advisory Committee Alerts	Email notification from the FDA when advisory committees are scheduled to discuss drugs, devices	X	X	X				
FDA Approval Alerts	Email notification from the FDA when drugs, devices and biologics and food additives are approved	X	X	X				
FDA Device Daily Bulletin	Daily e-newsletter reporting on FDA regulatory, legislative and business news developments in the medical device industry		X					



Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
FDA Drug Daily Bulletin	Daily e-newsletter reporting on regulatory, legislative and business news developments in the pharmaceutical industry			X				
Fierce Markets Network 2,4,8,10	Series of daily email newsletters on a range of health care topics including biotechnology, devices, pharmaceutical, health information technology and reimbursement issues	X	X	X		X		
Forbes 2,4,8	Biweekly business news magazine	X	X	X	X	X	X	X
Fortune 2,4,8	Biweekly news magazine focusing on political, economic and social issues related to business	X	X	X	X	X	X	X
Genome Medicine 1	Online peer-reviewed journal which publishes open access research articles in all areas of medicine studied from a genomic or post-genomic perspective. The journal has a special focus on the latest technologies and findings that have an impact on the understanding and management of human health and disease	X		X	X	X		X
The Gray Sheet 2,4,8	Weekly newsletter reporting on regulatory, legislative and business news relating to the medical device industry		X					X
Gynecologic Oncology 1	International journal devoted to the publication of clinical and investigative articles that concern tumors of the female reproductive tract. Investigations relating to the etiology, diagnosis, and treatment of female cancers, as well as research from any of the disciplines related to this field of interest, are published		X	X	X	X		X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Health Affairs 1, 4, 5, 6	A monthly peer-reviewed journal of health policy thought and research exploring health policy issues of current concern in both domestically and internationally.						X	
Health Imaging & IT 2,4,11	Online newsletter covering news and business issues related to imaging technologies		X			X		X
Health Leaders Media 2, 5, 5, 8	Information on management trends, innovations, market strategies, and organizational development for health care executives and professionals						X	
Healthcare IT News 2,4,8,10	Monthly newsletter includes new technologies, IT strategies and tactics, statutory and regulatory issues, as well as provider and vendor updates. Published in partnership with HIMSS		X				X	X
iHealthBeat 2,4,	Online newsletter reporting technology's impact on health care		X				X	X
Imaging Economics 2, 3, 4, 8	Monthly magazine providing information on the development, diffusion, acquisition, and utilization of imaging technology.to radiologists, radiology administrators, and executives		X			X	X	X
Imaging Technology News 2, 8	Bimonthly newsletter containing product information, technology trends, application strategies and related connectivity solutions in the medical imaging and radiation oncology markets		X			X		X
iMedicalApps 4, 6, 8	An independent online medical publication written by a team of physicians and medical students who provide commentary and reviews of mobile medical technology and applications		X			X	X	

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Institute for Healthcare Improvement 1, 4	An independent not-for profit-organization focusing on motivating and building the will for change; identifying and testing new models of care in partnership with both patients and health care professionals; and ensuring the broadest possible adoption of best practices and effective innovations.						X	
In Vivo 2, 4, 8	Monthly business resource for the biopharma, medtech, and diagnostics industries. Covers future industry trends, key industry developments, research and development of drugs and pharmaceuticals and regulatory issues	X			X		X	X
International Journal of Healthcare Technology and Management 1, 11	Bimonthly, peer-reviewed journal covering technology assessment and management, innovation and new product development		X				X	X
JAMA 1, 2, 4, 5	Weekly, peer-reviewed journal covering all areas of medical research	X	X	X	X	X	X	X
Journal of Clinical Psychiatry 1, 2	Peer-reviewed journal publishing medical research in all areas relating to mental health. Also covers newest advances in the diagnosis and treatment of mental disorders		X	X		X	X	X
Journal of Health Services Research and Policy 1, 4	Peer-reviewed journal covering the ideas, policies and decisions shaping health services throughout the world. Examines current issues in health care policy and research	X	X	X	X	X	X	X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Journal of Medical Devices 1, 2	Quarterly peer-reviewed journal focusing on applied research and the development of new medical devices that improve diagnostic interventional and therapeutic treatments. It provides special coverage of novel devices that allow new surgical strategies, new methods of drug delivery, or possible reductions in the complexity, cost, or adverse results of health care		X					X
Journal of Pediatrics 1	International, peer-reviewed journal of pediatric research. Geared toward the clinician. Covers the latest developments in pediatric medicine	X	X	X	X	X	X	X
Kaiser Family Foundation publications 1,2, 4, 5	A leader in health policy and communications, the Kaiser Family Foundation is a non-profit, private operating foundation focusing on the major health care issues facing the U.S., as well as the U.S. role in global health policy. Kaiser develops and runs its own research and communications programs, sometimes in partnership with other non-profit research organizations or major media companies	X	X	X	X	X	X	
LabMedicine 2	Monthly publication of the American Society for Clinical Pathology. Covers current and future trends in clinical laboratory medicine	X			X			X
Lancet 1,4,5	Weekly, peer-reviewed journal that publishes clinical trials results, research and analysis in all fields of medical research	X	X	X	X	X	X	X
MDLinx 1, 2, 11	Daily aggregate of medical articles and research from peer-reviewed journals and news media	X	X	X	X	X	X	X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Med Tech Insight 2, 4,	Newsletter providing business intelligence and insight in the medical technology industry; analyzes current markets and future trends in the industry, including technologies, clinical applications, key players, and start-up companies		X			X		
MedGadget 2,3, 4, 6, 8	Internet journal of emerging medical technologies		X					X
Medical Device Daily 2, 9, 10	Covers new product developments, company news, regulatory activity, legislative actions, strategic alliances, sales and mergers and market updates		X			X		X
MedicalPhysicsWeb 2, 4, 5, 6, 8	Website and “scientific web community” from IOP; provides access to information on biomedical physics; provides links to relevant original research		X			X		X
Medpage Today [Includes conference coverage] 2, 4,5, 6, 9, 11	Targeted to physicians. Provides a clinical perspective on breaking medical news read by consumers. Co-developed by MedPage Today and The University of Pennsylvania School of Medicine, Office of Continuing Medical Education, each article alerts clinicians to breaking medical news, with summaries and actionable information enabling them to better understand the implications	X	X	X	X	X	X	X
Medscape 1, 2, 9, 11	Resource for Physicians: medical journal articles, MEDLINE, medical news, major conference coverage drug information	X	X	X	X	X	X	X
MedWorm 1,2,3,4,5,6	A medical RSS feed provider and search engine that collects updates from over 6000 authoritative data sources	X	X	X	X	X	X	X
MIT Technology Review 2, 4, 5, 6, 7, 8	Magazine providing information on emerging technologies & impact on business & society	X	X					X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Neurology 1,4,5	Journal of the American Academy of Neurology (AAN).	X	X	X	X	X		X
Neurosurgery 1, 2	Official Journal of the Congress of Neurological Surgeons. Reports on research in neurosurgery and the latest science, technology, and medicine		X			X		X
New England Journal of Medicine 1, 2, 4, 5, 7, 9	Peer reviewed medical journal featuring current research information, reviews and articles for biomedical science, internal medicine and clinical practice	X	X	X	X	X	X	X
New Zealand Evidence Based Healthcare Bulletin 1, 2	Online publication is a joint initiative of the New Zealand Guidelines Group (NZGG) and the New Zealand Branch of the Australasian Cochrane Centre. Summarizes news and information about evidence-based health care activities in New Zealand and overseas. Each issues focuses on one particular medical topic	X	X	X	X	X	X	X
NHS HTA publication update	Email alert outlining new research publications as well as research agendas covering devices and technology							X
Obesity 1,2,4,5	Official journal of The Obesity Society. Publishes peer-reviewed research and cutting-edge reviews, commentaries, public health and medical developments relating to obesity		X	X		X		X
Oncology 1, 2, 4, 5,	Peer reviewed research journal. Purpose is to advance clinically-relevant knowledge of cancer, and improve the outcome of prevention, diagnosis and treatment. Publishes clinical studies translational laboratory findings, mini-reviews and controversial topics in oncology; also focuses on rapid peer-review and subsequent publication of short reports of phase 1 and phase 2 clinical cancer trials	X	X	X	X	X		X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Orthopedics 1, 2, 4,5,	Peer-reviewed journal that offers in depth information on research on orthopedics; is part of OrthoSuperSite.com	X	X	X	X	X		X
Orthopedics This Week 2, 4	Weekly News, Analysis and Commentary of orthopedic developments, both in the United States and Europe	X	X	X		X		X
OrthoSuperSite.com 1, 2, 4, 6, 7, 8, 9	Website offering access to all varieties of information on orthopedics from scientific and medical research to industry news	X	X	X		X		X
Pain Research and Management 1	Official journal of the Canadian Pain Society. Peer reviewed journal publishing original research and review articles pertaining to pain management		X	X	X	X		X
Personalized Medicine Coalition (PMC) Newsletter 2	E newsletter that reports on the development and adoption of personalized medicine including regulatory and industry news	X			X	X		X
PharmaManufacturing.com 2, 6, 8	Digital magazine reporting on industry news in pharma manufacturing			X				X
Pink Sheet 2,4,8	Weekly newsletter reporting on regulatory, legislative and business news relating to the pharma industry			X				X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
PLoS Medicine 1, 2, 4, 6	Peer-reviewed open access journal that publishes medical research	X	X	X	X	X	X	X
PlosCurrents 1, 4, 5	Open-access publications for the extremely rapid communication of new research findings currently covering Huntington's disease, genomic testing and influenza.	X		X	X			
Psychiatric News 2, 4, 5, 7	Bimonthly newspaper of the American Psychiatric Association (APA); the principal and official means of communication between APA and its members about policies, politics, and legislative and judicial issues plus clinical and research news affecting psychiatry		X	X		X		
Psychiatric Times 1, 2, 4, 5, 6, 11	Monthly psychiatric magazine from UBM Media		X	X		X		
Radiology Today 2, 6	Biweekly news magazine targeted to radiology professionals covering medical, industry and product developments		X			X		X
Radiotherapy and Oncology 1, 5	Peer-reviewed journal covering radiation oncology	X	X			X		X
ReachMD 2	Medical news and information for health care practitioners on new research, treatment protocols and continuing education requirements, Online and radio programming via XM Satellite Radio Channel.	X	X	X	X	X	X	X
Robert Wood Johnson Foundation 1, 4	A philanthropy that funds and produces knowledge, new ideas and expertise to improve health and health care.					X	X	
RT Image 2, 4, 6 8, 9	Weekly online and print network containing editorials, and articles for Radiologist, Radiographers & Radiology professionals		X			X		X



Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Start-up 2, 8	Monthly. Profiles new product companies, identifies the hottest technology areas, reviews funds flowing into private companies and investment trends, and reports on university tech transfer licensing. Industries covered: pharmaceuticals, biotechnology, medical equipment & devices, and in vitro diagnostics			X				X
TCT 2010	TCT (Transcatheter Cardiovascular Therapeutics) is the world's largest educational meeting specializing in interventional cardiovascular medicine		X			X		X
TEC Assessments 1	Blue Cross and Blue Shield Association's Technology Evaluation Center (TEC) provides evidence-based reports on health care technology assessment in the areas of diagnosis, treatment, management and prevention of disease	X	X	X	X	X	X	
Telemedicine and e-Health 1,2,8	Covers all aspects of clinical telemedicine practice, technical advances, medical connectivity, enabling technologies, education, health policy and regulation and biomedical and health services research dealing with clinical effectiveness, efficacy and safety of telemedicine and its effects on quality, cost and accessibility of care, medical records and transmission of same		X			X	X	X
The New York Times 2, 3, 4, 5, 7	Comprehensive health information on newly emerging technologies	X	X	X	X	X	X	X
theheart.org 2, 3, 4, 5, 9	Daily information on caring and prevention of disorders of the heart and circulation from Medscape	X	X	X	X	X	X	X

Resource Name and Type (1-11; see Key at end of Table)	Description	Biologics Biotech	Device	Drug	In Vitro Diagnostics	Procedure/ Therapy	Process	Off-label Use
Therapeutics Daily 2, 8	Daily news and information focusing on the development, sales, and marketing of major therapeutic categories - Cardiovascular, Oncology, Pain & Inflammation, Central Nervous System, and Infectious Disease	X	X	X	X	X	X	X
Thomson Reuters 2, 3, 8	Pharma, Integrity and Forecast news sections updated daily	X		X				
Wall Street Journal 2, 4, 5, 6, 7	Comprehensive health information on newly emerging technologies	X	X	X	X	X	X	X

**Key to Resource Type**

- 1: Original research and scientific reviews
- 2: News
- 3: Press Releases
- 4: Commentary
- 5: Editorial
- 6: Blogs
- 7: Letters
- 8: Product information
- 9: Education/ CME
- 10: Coverage Decisions
- 11: Conference reports

**Table 2. Databases to be searched**

Resource	Biologics/Biotechnology	Devices	Drugs	In Vitro Diagnostics	Procedures	Process
Embase	X	X	X	X	X	X
EuroScan	X	X	X	X	X	X
Healthcare News, current (Lexis- Nexis)	X	X	X	X	X	X
PRNewswire*	X	X	X	X	X	X
PsycINFO	X	X	X	X	X	X
PubMed/Medline	X	X	X	X	X	X
Thomson Reuters Databases	X		X	X		

**Table 3. Example of an initial Embase filter for broad exploratory search of a priority area**

Set number	Concept	Search Statement
1	Stroke (part of cardiovascular priority area)	*stroke/ or (stroke or cerebrovascular accident or brain attack).ti.
2	Publication types likely to yield content for Healthcare Horizon Scanning System	conference paper/ or feasibility study/ or preliminary communication/ or trend study/
3	Keywords likely to yield content for Healthcare Horizon Scanning System	Advances.ti. or development\$.ti. or emerging or feasibility or (first adj2 class) or (first adj2 man) or future or horizon or investigational or new.ti. or novel or pilot or pipeline or (proof adj2 principle) or translational or trend\$
4	Combine sets	1 and (2 or 3)
5	Limit	4 and (human/ or humans/)

**Table 4. Examples of initial PubMed filters for broad exploratory searches for process and health care delivery innovations**

Set number	Concept	Search Statement
1	Innovation	Change agent* OR opinion leader* OR champion[tiab] OR “social networks” OR “learning collaborative”
2		Diffusion of innovation[mh] OR organizational innovation[mh] OR innovat*[ti]
3		Problem solving[mh] OR creativity[mh]
4	Combine sets	#1 OR #2 OR #3
5	Delivery of health care	Delivery of health care[mh] OR health services[mh] OR health services administration[mh]
6		Organizational AND (“case studies” OR culture)
7	Combine sets	#5 OR #6
8	New therapies	(New OR novel OR trend*)[ti] OR trends[sh]
9		Therapy[sh] OR diagnosis[sh]
	Combine sets	#8 AND #9

**Table 5. Initial Leads List**

<b>AHRQ Priority Area</b>
<b>00 Unclassified</b>
<b>01 Arthritis and nontraumatic joint disease</b> Examples of subcategories: Arthritis, Gout, Spine, Neck, Ankle, Knee, Hip, Elbow, Wrist, Finger
<b>02 Cancer</b> Examples of subcategories: Biliary, Breast, Colon, Kidney, Liver, Lung, Ovarian, Pancreas
<b>03 Cardiovascular disease</b> Examples of subcategories: Aneurysms, Arrhythmias, Coronary Artery Disease, Heart Failure, Peripheral Vascular Disorders, Stroke, Varicose Veins
<b>04 Dementia (including Alzheimer's)</b> Examples of subcategories: Alzheimer's, Frontotemporal, Lewy body, Vascular dementia
<b>05 Depression and other mental health disorders</b> Examples of subcategories: Anxiety disorders, Bipolar disorder, Major Depressive Disorder, Eating Disorders, Obsessive Compulsive Disorder, Post-traumatic Stress Disorder, Schizophrenia
<b>06 Developmental delays, attention-deficit hyperactivity disorder, and autism</b> Examples of subcategories: Attention Deficit Disorders (ADD, ADHD), Autism Spectrum Disorders, Developmental Delays
<b>07 Diabetes mellitus</b> Examples of subcategories: Type 1, Type 2, Metabolic Syndrome
<b>08 Functional limitations and disability</b> Examples of subcategories: Degenerative Disorders (e.g., MS, ALS, Muscular Dystrophy); Endocrine Dysfunction, Congenital Metabolic Disorders, Pain, Burns, incontinence and Elimination Disorders; Sensory Conditions (e.g., Vision Disorders, Hearing disorders, Vertigo, Pain)
<b>09 Infectious disease including HIV-AIDS</b> Examples of subcategories: Bacterial (TB, Meningitis), Fungal, Viral (HIV, HBV, HCV, HPV, Influenza), Hospital-acquired infections (MRSA, C.Diff)
<b>10 Obesity</b>
<b>11 Peptic ulcer disease and dyspepsia</b> Examples of subcategories: Bowel diseases (e.g., Inflammatory Bowel, Crohn's), Gastroesophageal Reflux (GERD), Motility Disorders
<b>12 Pregnancy, including preterm birth</b> Examples of subcategories: Premature Infants, Fetal Surgery, Contraception, Fertility & Infertility
<b>13 Pulmonary disease, asthma</b> Examples of subcategories: Chronic Obstructive Pulmonary Disease, Cystic Fibrosis, Emphysema
<b>14 Substance abuse</b> Examples of subcategories: Alcohol, Cocaine, Opioids, Tobacco
<b>15 Cross cutting</b> Examples of subcategories: Diagnostic imaging, general care delivery innovations

## Appendix B. Horizon Scanning Structured Comment Form

[Topic Title and Unique Identifying Number] (Each form is for a specific topic)

All fields denoted with an asterisk \* must be completed in order to submit this form.

### EXPERT'S CONTACT INFORMATION

Expert's Name \*  
Job Title \*  
Academic, Professional, and Manufacturer Affiliations \*  
Preferred mailing address \*  
Email address \*  
Telephone \*  
Fax  
Best times to reach you

### CONFLICTS OF INTEREST DISCLOSURE

Please disclose below any potential intellectual or financial conflicts of interest, such as research in progress, consulting arrangements, or other financial involvements with companies related to technologies, services, or programs evaluated in this draft. \*

Do you consult for developers or manufacturers that do or would compete with this intervention? \*

Yes    No

If yes, please describe the nature of your consultation below.

### HORIZON SCANNING TOPIC COMMENT FORM

Please use the guidance below to rate the potential of [topic title] for each of the 7 parameters described. Please provide your rationales for each rating. These parameters are intended to serve as anchoring points for considering the overall potential impact of the intervention or program. Your rationales will provide critical perspectives.

**1. For [Horizon Scanning topic, #####], Potential Importance of the Unmet Need it Intends to Address\***

Consider here only whether a gap exists in health care needs that [Horizon Scanning topic] could potentially address and how important you think that gap is. (Do not limit to the size of the population affected; other considerations include magnitude of purported benefit; whether other options exist and the benefits and harms of those options.) Provide your rationale. \*

1	2	3	4
Not important	Small importance	Moderate importance	Very important

Rationale: \*

## 2. For [Horizon Scanning topic, #####], Potential to Improve Patient Health\*

Consider the scientific and/or clinical validity of the developer's claims and purported benefits for [Horizon Scanning topic]. Are the claims sound? Does the underlying theory/concept and the preliminary data reported by investigators thus far support the claim? How convinced are you about its potential to improve patient outcomes? What gaps between the theory or claims and early data concern you the most?

Provide your rationale. \*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>None</b>	<b>Small</b>	<b>Moderate</b>	<b>Large</b>

Rationale: \*

## 3. For [Horizon Scanning topic, #####], Potential to Affect Health Disparities\*

Do you think this intervention could potentially affect health disparities? We define disparity as a climate in the health care system that creates differences in access to, use of, and quality of care such that it affects health status or patient-oriented health outcomes. In what ways, e.g., would it increase or decrease disparities and access? \*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>None</b>	<b>Small</b>	<b>Moderate</b>	<b>Large</b>

Rationale: \*

## 4. For [Horizon Scanning topic, #####], Potential to Disrupt the Healthcare Delivery System\*

What potential do you think [Horizon Scanning topic] has to disrupt how patients are managed and how clinicians and health systems approach the condition/disease/problem? Issues to consider include: care process changes when it is implemented; length of patient stay; numbers of patients that can be treated; amount of care that needs to be delivered; amount of care that can be avoided; shift in care setting from inpatient to outpatient or to home care or one department to another; change in infrastructure needs, such as physical resources (e.g., facility expansion or contraction, impact on use of shared resources within a facility or health system, capital equipment acquisition or obsolescence, expenditures or savings), and staffing resources (e.g., increases/decreases, staffing mix required, patient throughput handled by staff).

Provide your rationale. \*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>No disruption</b>	<b>Small disruption</b>	<b>Moderate disruption</b>	<b>Large disruption</b>

Rationale: \*

## 5. For [Horizon Scanning topic, #####], Potential for Acceptance/Adoption by Patients and Clinicians\*

Consider factors that could affect willingness to use [Horizon Scanning topic], such as, but not limited to, convenience/ease of use and learning curve to use it, ease of acquisition, ease of compliance, degree of invasiveness, degree of physical and mental capacity required for use, anticipated side effects, risks, adverse events. Please also highlight any potential controversies you foresee [Horizon Scanning topic] generating. Provide your rationale.

**By Clinicians\***

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
<b>No acceptance</b>	<b>Low acceptance</b>	<b>Moderate Acceptance</b>	<b>Wide Acceptance</b>

**Rationale\***

**By Patients\***

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
No acceptance	Low acceptance	Moderate Acceptance	Wide Acceptance

**Rationale:\***

**6. For [Horizon Scanning topic, #####], Potential Impact on Healthcare Costs\***

How might [Horizon Scanning topic] affect costs of care for the intended patients and health care system? Please note how you expect costs to change and for whom (e.g., patients, payers, health care facilities). Do you anticipate that any of the potential changes in cost would generate controversy? What kind of controversy? Provide your rationale.\*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
None	Small impact	Moderate Impact	Large impact

**Rationale:\***

**7. For [Horizon Scanning topic, #####], Overall Potential to Fulfill the Unmet Need?\***

Given your considerations about all the parameters you have responded to, what do you think is the overall potential of [Horizon Scanning topic] to fulfill the unmet need(s) it purports to address? Provide your rationale.\*

<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>
None	Small	Moderate	Large

**Rationale:\***

**Additional Comments (Please limit to 1000 characters):**

**Note:** All fields denoted with \* must be completed in order to submit this form. If the form does not advance to a 'confirmation page' when the 'Submit' button is clicked, please scroll up and complete any remaining blank fields indicated by 'response required' text.